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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,854	08/25/2003	Orest W. Blaschuk	100086.402C2	3628
	7590 03/27/200 ECTUAL PROPERTY	EXAMINER		
701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			RUSSEL, JEFFREY E	
			· ART UNIT	PAPER NUMBER
52		1654		
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		03/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Application No.	Applicant(s)			
		10/648,854	BLASCHUK ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Jeffrey E. Russel	1654			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING Dominions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period or re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDON	DN. timely filed m the mailing date of this communication. IED (35 U.S.C. § 133).			
Status						
2a)⊠	Responsive to communication(s) filed on <u>13 N</u> This action is FINAL . 2b) This Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final. nce except for formal matters, p				
Dispositi	on of Claims					
5) □ 6) ⋈ 7) □ 8) □ Applicat i 9) □ 10) ⋈	Claim(s) 192-200 is/are pending in the applica 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 192-200 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or con Papers The specification is objected to by the Examine The drawing(s) filed on 25 August 2003 is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine	wn from consideration. or election requirement. er. a) \(\sum \) accepted or b) \(\sum \) objected drawing(s) be held in abeyance. Stion is required if the drawing(s) is consideration.	ee 37 CFR 1.85(a). Objected to. See 37 CFR 1.121(d).			
Priority ı	ınder 35 U.S.C. § 119		·			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
2) Notice 3) Information	t(s) te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date	4) Interview Summa Paper No(s)/Mail 5) Notice of Informa 6) Other:				

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1. Applicant's election of SEQ ID NO:10 from Group (A) and the sequence RGD from Group (B) in the reply filed on May 17, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

- 2. The Sequence Listing filed November 13, 2006 is approved.
- 3. The terminal disclaimer filed November 13, 2006 is approved.
- 4. Claims 192-200 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The interpretation of the length limitation inserted into claim 192 is unclear. Because the independent claim requires the presence of at least two HAV sequences in the linear peptide, and because dependent claims 197 and 200 recite that the linear peptide can further comprise a sequence identified as SEQ ID NO:31 (which comprises 48 amino acids), the length limitation can not be met when the linear peptide comprises the sequence identified as SEQ ID NO:31. Further, dependent claim 194 specifies that the linear peptide can be linked to a targeting agent. Applicants' specification discloses that the targeting agent can be a peptide (see, e.g., page 36, lines 9-17) and discloses that the linker can be amino acids or a peptide (see, e.g., page 18, lines 1-2). When the linear peptide is linked to a targeting agent and/or a linker which are polypeptides, it is not clear how it is determined whether or not the length limitation is met, because assignment of a particular amino acid in a peptide to the linear peptide portion, targeting agent portion, or linker portion appears to be relatively arbitrary. The prior art rejection over Tripp et al (U.S. Patent No. 6,419,923) set forth below shows the uncertainty in determining whether Applicants' length limitation is met by a prior art peptide.

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5. Claim 193 is objected to under 37 CFR 1.75(c), as being of improper dependent form for

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- failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 192 requires the presence of the amino acid sequence His-Ala-Val in the linear peptide. Independent claim 192 does not indicate that derivatives of the sequence His-Ala-Val can be present in the linear peptide instead of His-Ala-Val per se. Dependent claim 193 recites that the linear peptide can comprise "derivatives of the foregoing sequences", where the derivatives can have side chain modifications and the foregoing sequences include HAV and other HAV-containing sequences. Accordingly, it appears that claim 193 embraces the use of linear peptides which do not comprise His-Ala-Val, and thus embraces the use of linear peptides not permitted by independent claim 192.
- 6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 7. Claims 192-200 are rejected under 35 U.S.C. 102(e) as being anticipated by Tripp et al (U.S. Patent No. 6,419,923). Tripp et al teach a protein of SEQ ID NO:15, which comprises two copies of the partial sequence His-Ala-Val at residues 317-319 and 354-356, and the partial sequence Arg-Gly-Asp at residues 309-311. Trip et al teach the protein in combination with a pharmaceutically acceptable carrier, and teach administering the protein in vivo to a mammal. See, e.g., column 3, lines 15-22; column 11, lines 23-25; column 20, lines 8-14 and 52-67; column 21, lines 11-31; and claims 1, 5, and 6. The two HAV sequences and the RGD sequence present in the protein of Tripp et al occur within a 48-amino acid fragment of the protein. This 48-amino acid fragment corresponds to the linear peptide recited in Applicants' claims, and thus

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Applicants' length limitation is deemed to be met by the protein of Tripp et al. The fragments of Tripp et al's protein occurring at positions 1-308 and 357-407 correspond to targeting agents and/or linkers which are permitted to be attached to the linear peptide in accordance with Applicants' claims (see also the above rejection under 35 U.S.C. 112, second paragraph). The partial sequence Arg-Gly-Asp present in the protein of Tripp et al also corresponds to Applicants' targeting agent and to Applicants' cell adhesion recognition sequence bound by an adhesion molecule other than a classical cadherin. Residues 312-316 of the protein of Tripp et al corresponds to Applicants' linker of claim 196. The mammals of Tripp et al inherently comprise cells expressing cadherins. Because the same linear peptide is being contacted with the same cells expressing cadherins according to the same method steps, inherently cell adhesion will be modulated in the method of Tripp et al to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Tripp et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than the method of Tripp et al. With respect to instant claim 193, to the extent that the claim permits without limitation derivatives of the sidechains of Applicants' SEQ ID NOS:10 or 11, the protein of Tripp et al meets the claim limitation.

8. Applicant's arguments filed November 13, 2006 have been fully considered but they are not persuasive.

The objection to dependent claim 193 set forth in section 5 of the previous Office action is repeated in section 5 above. Applicants' amendment did not contain any alteration to the "derivatives" limitation occurring in the claim. In view of the "derivatives" language, it appears that the linear peptide can comprise an amino acid sequence in which any and/or all of the amino

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acid residues recited in Applicants' SEQ ID NO:10 or SEQ ID NO:11 can be altered, i.e. that the peptide need not comprise either HAVHAV or SHAVSHAVS. Such a peptide is not embraced within the scope of the independent claim.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

March 21, 2007